

**REMARKS**

Claims 1, 2 and 8 are pending in the application

The Examiner has withdrawn the previous §103 obviousness rejection based on the combination of Sato et al, EP 1 211 242, and Sato et al, JP 2001-151749 and made a new obviousness rejection based on Sato et al, WO 01/197790.

Claims 1, 2 and 8 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sato et al, WO 01/197790.

Applicants traverse the rejection.

WO '790 is the publication of the International Application on which Sato EP '242 is based and therefore WO '790 is considered to be equivalent to that of Sato '242. Applicants submit that the rejection based on WO '790 is improper for the reasons of record with respect to Sato '242. Namely, WO '790 lacks the ethynylene group in the sulfur containing substituent on the cyclopentane ring and there is no teaching or suggestion to modify the compounds of formula (I) in WO '790 to arrive at the compound of formula (I) recited in the present claims. Further, the sleep inducing effects of the present compounds could not have been expected without this feature as discussed in the Response filed April 30, 2009.

In the Office Action dated August 5, 2009, WO '790 is cited allegedly to show a sleep-inducing prostaglandin derivative of formula (I) wherein Y may be ethylene, m may be 0 and A may be  $S(O)_p(CH_2)_n$  wherein p may be 0 and n may be 1-5. The Examiner, particularly points to Compound 19 as being an "adjacent homologue". While the term "adjacent homologue" is not necessarily clear in its precise definition, the claimed compounds do differ from Compound 19 with respect to their sulfur containing side chains. Compound 19 lacks an ethynylene group in

the side chain. Specifically, the side chains of the claimed compounds are S-(CH<sub>2</sub>)<sub>2</sub>-≡-CO<sub>2</sub>H; the side chain of Compound 19 is -S-(CH<sub>2</sub>)<sub>3</sub>-CH<sub>2</sub>-CO<sub>2</sub>H. Although the total numbers of the carbon atoms intervened between the sulfur atom and the carboxyl group are the same (four), both compounds should not be referred to as "homologues" because of the presence of the ethynylene group.

Thus, Compound 19 at least is not an "adjacent homologue." Further, there is no teaching or suggestion to introduce the ethynylene group in the sulfur-containing side chain in the disclosure of WO '790.

In the Action of August 5, 2009, it is further indicated that "it would have been *prima facie* obvious at the time the invention was made to one of ordinary skill in the art to start with the generic teaching of WO '790, and especially in view of the close compound 19, to make other generically disclosed compounds where n is 1 and to expect to make sleep inducing compounds." On the contrary, Applicants submit that the Examiner has not met the burden of properly establishing a *prima facie* case. Specifically, the three basic criteria (for establishing a *prima facie* case of obviousness) have not been satisfied. First, as indicated above, there is no suggestion or motivation in WO '790 to modify WO '790. Second, there is no reasonable expectation of success. In the Response filed April 30, 2009, it was pointed out that "Prostaglandins are particularly characterized by a wide variety of physiological actions. --- Thus, to modify partial structures of a specific series of prostaglandins for the purpose of improving a property may result in the total loss of the property and instead the appearance of a different property. Such contemplated modifications often will bring about unpredictable results, where the likelihood of success with the aim at improving the property (such as sleep-inducing

activity) is not high." This is still true. Third, WO '790 does not teach or suggest all the claim limitations.

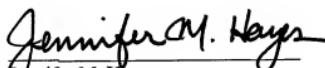
Accordingly, it would not have been obvious for one of ordinary skill in the art to try structural modifications with a reasonable expectation of success in arriving at the claimed compounds provided with proven sleep-inducing activity in the animal test, based on the disclosure of WO '790.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection based on WO '790.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

  
Jennifer M. Hayes  
Registration No. 40,641

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE  
**23373**  
CUSTOMER NUMBER

Date: December 4, 2009